In the Pharmaceutical industry, specifications are core which mandates for all programming activities. Currently, SDTM and ADAM specifications are configured manually by mapping the raw data to the standard domains. This paper proposes an automatic and efficient approach to configure certain parts of SDTM specifications using SAS macros. This enables the auto-population of mapping rules into the specification, significantly reducing the manual work and make our deliverables on time with higher quality.

**Introduction:**

Specification generation process is to integrate/map data for different studies of a compound into a common integrated database. The source data can be any standard, also company standards with different therapeutic area. By using sas macro templates and metadata, we can generate the SDTM spec without doing repetitive work for spec writing process.

**Metadata Creation:**

- **Source data:**
  - **DATASET**
    - **VARIABLE**
    - **REVERSIBLE**
    - **LABL**
    - **DATA TYPE**
    - **FORMAT**
  - **ASET**
    - **ADVERSE EXPERIENCE**
  - **AESEQ**
  - **AEENDTC**
  - **AEDE**
  - **AEDE**
  - **AEDE**

- **Metadata driven source to Target Transformations:**
  - **METADATA驅動源到目標轉換:**
    - **USUBJID**
    - **ASEQ**
    - **AETERM**
    - **AESTDTC**
    - **AENDT**

**Process Overflow:**

- **Look-Up Table:**
  - **To compare source data with metadata:**
    - Compare the variables in Source Dataset and Metadata using SAS Macro.
    - Where statement in macro filters the type of data collection which is based on each therapeutic area under company standards.
    - Create target domain table with matched variables and its transformation.
    - Check and update the generated specification manually for the variables which is not available in the Metadata.

**Advantages:**

- Allow the specification to adopt a uniform structure over all the studies.
- It will also facilitate Use and Re-Use of existing/previously Study based on rules in metadata.
- Reduce a considerable amount of time and manpower involved which in turn reduces the manual errors.

**Future amendment:**

To generate mapping specification for ADAM datasets with the use of standard metadata repository to get all the common variables for all the datasets.

**Conclusion:**

Creating SDTM specifications using SAS macros can eliminate most of the manual and repetitive work from the spec writing process. This Overall automation process produces more efficient, higher quality, and less error prone specifications.

**References:**